



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2016
EMA/CHMP/302887/2016

CHMP List of questions

To be addressed by Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6, Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, India and Micro Therapeutic Research Labs Pvt. Ltd, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641029, Tamil Nadu, India

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A31/1450
Tadalafil Mylan EMEA/H/A31/1450/C/003787/0005



At Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6 , Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, India and Micro Therapeutic Research Labs Pvt. Ltd, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641029, Tamil Nadu, India were subject to GCP inspections carried out in February 2016 by the Dutch and Austrian competent authorities where critical findings were identified on the inspected studies, as well as serious deficiencies in the quality management system in place at the site (covering clinical and bioanalytical activities), which affect the trustworthiness of the data generated by the site between June 2012 and June 2016 and cast doubt on the reliability of the corresponding bioequivalence studies conducted during this period to support a marketing authorisation.

The Micro Therapeutic Research Labs (MTR) is invited to provide the following information:

1. Any relevant and substantiated information to be considered by the Committee for Medicinal Products for Human Use (CHMP) when determining the impact of the inspection findings on the benefit-risk balance of medicinal products authorised, as well as for pending marketing authorisation applications, on the basis of trials performed since the set-up of the sites.
2. A list of marketing authorisations/ marketing authorisation applications in the European Union for which Micro Therapeutic Research Labs (MTR) has been involved in the clinical and/or bioanalytical activities in the context of bioequivalence studies.